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10/533,307

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Yukihiro Morinaga

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KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/533,307 | Applicant(s) MORINAGA ET AL. | |
| | Examiner TRISTAN J. MAHYERA | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-15 and 18-21 in the reply filed on 2/3/2009 is acknowledged.

Status of Claims

Claims 1-21 are pending. Claims 16 and 17 are withdrawn pursuant to 37 CFR 1.142(b), as being drawn to the non-elected invention. Claims 1-15 and 18-21 are examined on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d) is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by MATSUDA (EP 1022031, see PTO-1449).

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MASUDA teaches a suturable adhesion-preventing membrane that has high suture strength, good biocompatibility, decomposition and absorption in a living body comprising a nonwoven fabric layer made of collagen fibers, a sponge layer made of collagen and a coating or lamination layer made of gelatin. See e.g. abstract and claims 1-3. Since the fabric is made of collagen it is biodegradable: instant claims 1 and 2. The biodegradable thread is the suture that is used to stitch the fiber to a wound, see the use of such a thread in Examples 5 and 10: instant claims 1-3. The coating and/or laminate is a biodegradable material, specifically gelatin. See e.g. claims 1, 32 and 33: instant claims 13 and 14. The thread used in Examples 5 and 10 is 5-0 "bicryl" thread, believed to actually be a misspelling of 5-0 "vicryl" thread, which is an absorbable PGA derivative suture: instant claim 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over BELL et al. (US 6,153,292 see PTO-892 filed 1/6/2009).

BELL teaches biopolymer foams and sponges (i.e. filmy material) such as those made from collagen are applied to a nonwoven fabric whereby biopolymer threads are woven or braided (i.e. stitched) into the fabric. See col. 8 line 65 to col. 9 line 17: instant claims 1-3. The surface of the fabric or foam is coated with a biodegradable material, specifically extracellular matrix particles or a coating of collagen that includes the particles. See e.g. col. 3 lines 13-20 and 23-24: instant claims 13 and 14. The threads are composed of collagen. See e.g. col. 9 line 3: instant claim 15.

While BELL does not exemplify the instant invention it would have been obvious to a person of ordinary skill in the art to use the preferred embodiments of BELL to arrive at a nonwoven fabric and a filmy sponge or foam material coated or piled up on one another and where biopolymer or biodegradable collagen threads are stitched into

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the fabric to make the instant invention. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Claims 1, 2-15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MATSUDA as applied to claims 1-3, 13-15 above, and further in view of GOMI et al. (US 5,061,533, see PTO-892).

GOMI teaches placement of carbon fiber thread winding angles in order to increase rigidity and light weight. GOMI is used to show that the arranging direction of the threads and the acute angle between the arranging direction for the purpose of increasing the strength/rigidity of a material is dictated by Young's modulus, which as can be seen in Fig. 1 and Table 1 which shows angles of the thread or fiber orientation. If the innermost layer angle has an angle of 90 to ± 75 degrees, which reads on the angle in instant claims 4, 5, 7 and 8, then the outermost or third layer would have an angle of 0 to ± 35 degrees, which reads on the angle/arranging direction or interface in instant claims 4-6, 8 and 9. The threads or fiber can be clearly seen in a parallel configuration for each respective layer in Fig. 1 and a dotted pattern of diamonds is created by any pattern that overlaps (i.e. 2 and 3 in Fig. 1): parallel in instant claims 4, 5, 18 and 20 and dotted in claim 11. Multiple layers of at least 4 are adhered to or piled on top of one another (see col. 4 lines 30-34 and Fig. 1: instant claim 8) are further contemplated by GOMI, which reads on up to or greater than the nine layers in claims 18-20. Anytime the laminated fabric containing the collagen fiber/sponge (also a fabric)

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is sutured, the layers are penetrated by the thread and thus the suturing as done in Ex 5 and 10 of MATSUDA reads on claim 21.

The interval of the threads will be 0mm when each thread is directly next to its adjacent thread/fiber which would occur when the winding angle is approximately 0, which reads on claim 10. In addition, the interval of the threads would be obvious to a person skilled in the art because a closer interval would allow more thread to be attached to the fiber or substrate base, up to a maximum where the interval is 0, and therefore have a greater affect on rigidity and conversely a larger interval would allow for less thread and a corresponding loss of rigidity. The same reasoning applies to claim 20, where the intervals are at approximately 6mm (which 0mm reads on). Thus, the interval between threads would be determined by a person skilled in the art at the time of the invention and would not require excessive experimentation to arrive at such optimal intervals: instant claims 10 and 20.

The stitch intervals in claim 12, when interpreted as a distance between sutures (i.e. the biodegradable threads) are completely dependant on the use of the substrate and the necessary strength of attachment between one or more substrates and tissue or other materials. A person skilled in the art would be fully capable of determining the appropriate interval between stitches and the claimed range would have been present once the invention was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a biodegradable substrate wherein the arranging direction and acute angle of the threads are taught as specifically increasing the rigidity/strength

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or elongation by following angles and arrangements that affected Young's modulus as taught by MATSUDA in view of GOMI. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single substrate because of the beneficial effects of increasing rigidity and keeping weight light due to the thread angle and arrangement, as taught by GOMI. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615